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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/783,442 | 02/20/2004 | W. Robert Addington | 70538.UT | 7778 |

7590 05/07/2007
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| EXAMINER |
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HOEKSTRA, JEFFREY GERBEN

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| ART UNIT | PAPER NUMBER |
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3736

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| MAIL DATE | DELIVERY MODE |
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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/783,442 | Applicant(s) ADDINGTON ET AL. | |
| | Examiner Jeffrey G. Hoekstra | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/16/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 02/16/2007, amended claim(s) 9 is/are acknowledged. The current rejections of the claim(s) 9, 10, and 14-16 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 9, 10 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill et al (US 6,735,471).

5. For claims 9, 10, and 16, Hill et al discloses an apparatus as broadly as *structurally* claimed, comprising:

- a nebulizer capable of being actuated to atomize a cough-inducing substance contained therein (column 4 lines 5-23 and the drug delivery means positively recited in column 5 lines 22-26);

- an electrical switch (250) associated with said nebulizer and capable of being responsive to actuation of said nebulizer (column 16 lines 10-30);
- an EMG machine (230) having one or more EMG sensing electrodes (270) connecting to the patient for sensing muscular electrical activity and capable of measuring cough latency (Figure 9 shows the latency measurement between stimulation and bodily response events); and
- a connection comprising at least one wire between said switch and said EMG machine (the wires as best seen in Figure 1) capable of activating the EMG machine in response to said electrical switch.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al in view of Addington et al (US 6,655,376 B2). Hill et al discloses the claimed pulmonary stimulation and measurement apparatus, including delivering a drug composition into a patient, except for explicitly disclosing a cough-inducing substance containing one or more salts of tartaric acid including a composition made with up to 20% tartaric acid. Addington et al discloses a pulmonary stimulation and measurement apparatus comprising the use of a cough-inducing substance containing one or more salts of tartaric acid including a composition made with up to 20% tartaric acid (column 3 lines 23-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulmonary stimulation and measurement

apparatus as taught by Hill et al, with the pulmonary stimulation and measurement apparatus as taught by Addington et al for the purpose of increasing the efficacy of a desired drug-induced response via administered pharmacological agents to increase patient response during advanced medical procedures.

Response to Arguments

8. Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Conclusion

9. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Addington et al. (US 5,678,563 and 6,004,268) discloses the use of nebulized pharmacological cough stimulants to diagnose and measure a patient's cough-induced response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

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